

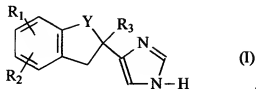
## REMARKS

This application has been reviewed in light of the Office Action dated December 9, 2009. Claims 1 and 3-18 are presented for examination, of which claim 1 is in independent form. Claim 2 has been cancelled and its recitations incorporated into claim 1, this action being taken without prejudice or disclaimer of subject matter. Claim 1 has been amended to better define Applicants' invention. Support for the amendment may be found in original claim 2. Applicants submit that no new matter has been added. Favorable reconsideration is requested.

The Examiner objected to the dependency of claim 4. Applicants have amended claim 4 herein to properly depend from claim 3. Therefore, Applicants request withdrawal of the objection.

Claims 1, 3-4, 12-15 and 17-18 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,292,887 (Karjalainen). Claims 1, 3 and 12-18 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Karjalainen. Applicants respectfully traverse the rejections.

Prior to addressing the grounds of rejection, Applicants wish to briefly review certain features and advantages of the presently claimed invention. The invention is directed, in pertinent part, to a fast-dispersing, solid dosage form formulated to disintegrate within 10 seconds of being placed in the oral cavity containing, as an active ingredient, a substituted imidazole derivative of general formula (I),



so as to promote pre-gastric absorption of the active ingredient. The invention relates to an improved formulation containing a substituted imidazole derivative. In the past, substituted imidazoles have shown disadvantages, such as quick decomposition in the stomach, which lowers the effect of the composition, and transient adverse reactions, such as white spots and numbness. Page 1, line 18 through page 2, line 10 of the subject specification as filed. The inventors of the subject invention discovered that if the compounds of formula (I) are administered in a fast-dispersing solid dosage form, so that they are absorbed through the oral mucosal membrane, or otherwise pre-gastrically, many of these disadvantages can be avoided and bioavailability improved. See page 2, lines 13-16. The fast-dispersing dosage form sustains the active ingredient in the buccal, sublingual, pharyngeal and/or oesophageal mucus membranes so that the absorption is pre-gastric and thereby leading to medical benefits.

Karjalainen is directed to substituted imidazole derivatives. As disclosed therein, the compounds “may be administered orally, parenterally or intravenously.” Karjalainen fails to disclose or suggest use of the imidazole derivatives in a fast-dispersing, solid dosage form, the benefits of pre-gastric absorption of the active ingredient, or the potential to use the compound in a form which disintegrates within 10 seconds of being placed in the oral cavity. Simply indicating that the compound may be administered orally does not indicate, nor in any way realize, the benefits of administering the drug so that it is absorbed pre-gastrically. Further as shown at page 12, lines 4-9 of the subject specification as filed, oral dosing of fipamezole, an imidazole derivative, shows unsatisfactory bioavailability. Since Karjalainen fails to recognize administration by fast-dispersing, solid dosage form, it further fails to realize that this leads to improved bioavailability.

On page 3 of the Office Action, the Examiner alleges that Karjalainen discloses a solid dosage form and that it would be “inherent that the exposure to bile juices would fast disperse the solid dosage form.”

Applicants respectfully submit that whether the dosage form of Karjalainen disperses upon contact with bile is not relevant to the present invention. The presently claimed invention discloses a dosage form whereby the active ingredient is absorbed pre-gastrically by virtue of the fast-dispersing solid dosage form. In the present invention, the active ingredient is intended to be absorbed within 10 seconds in the mucus membranes in the mouth or the pharynx and/or oesophageal mucus membranes, i.e., prior to reaching the bile of the duodenum (small intestine). Karjalainen fails to teach or suggest administering the active in the fast-dispersing solid dosage form of the presently claimed invention.

Also at page 3, the Examiner alleges that the network of claim 3 carries no patentable weight. Applicants respectfully disagree.

The network structure of claim 3 is one manner in which to achieve the fast dispersing property of the present invention. A network formed by lyophilization has a low density, highly porous structure, which rapidly imbibes saliva and disperses in the mouth, without the requirement for additional solvent addition. Therefore, the process by which the fast-dispersing solid dosage form is made creates a unique network which confers to the dosage form the ability to disintegrate within 10 seconds. For at least these reasons, Applicants respectfully submit that the “network” of claim 3 should be awarded patentable weight.

In sum, Karjalainen fails to teach or suggest all of the features of the presently claimed invention, namely, a fast-dispersing, solid dosage form for pre-gastric absorption of the active ingredient, which disintegrates within 10 seconds of being placed in the oral cavity.

Therefore, Applicants submit that Karjalainen does not anticipate or render obvious the presently claimed invention.

Claims 1, 4-6 and 8 were also rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Karjalainen, in view of U.S. Patent No. 4,968,692 (Linnoila); claims 1-6 and 8-11 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Karjalainen, in view of U.S. Patent No. 6,316,027 (Johnson); and claims 1-18 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Karjalainen, in view of U.S. Patent No. 6,709,669 (Murray). Applicants respectfully traverse the rejections.

For all of the reasons set forth above, Karjalainen fails to render the presently claimed invention obvious. Further, Linnoila, Johnson and Murray fail to remedy the deficiencies of Karjalainen. Linnoila suffers from the same deficiency as Karjalainen – there is simply no teaching or suggestion of a fast-dispersing, solid dosage form for pre-gastric absorption of the active ingredient, which disintegrates within 10 seconds of being placed in the oral cavity. Johnson and Murray are also deficient insofar as they provide no reasonable expectation of success that the fast-dispersing dosage forms disclosed therein could be used for the presently claimed substituted imidazole derivatives.

In sum, Applicants submit that the present invention is not rendered obvious by Karjalainen, Linnoila, Johnson or Murray, whether considered separately or in any permissible combination. There is simply no disclosure or suggestion in the cited art of a presently claimed fast-dispersing, solid dosage form containing, as an active ingredient, a substituted imidazole derivative, which promotes pre-gastric absorption and disintegrates in 1-10 seconds. For at least these reasons, Applicants respectfully request withdrawal of the §103 rejections.

Claims 1-18 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 23 and 25-33 of co-pending U.S. Patent Application No. 10/534,091. Applicants submit that the applications are directed to non-obvious variations and respectfully request withdrawal of the rejection.

As amended herein, claim 1 is directed to a fast-dispersing, solid dosage form, which disintegrates within 10 seconds of being placed in the oral cavity. This dosage form is specifically utilized to impart quick release characteristics to the subject invention. Since the claims of U.S. Patent Application No. 10/534,091 fail to recite or suggest this limitation, the subject invention is not rendered obvious therefrom. Withdrawal of the provisional double-patenting rejection is respectfully requested.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

Applicants' undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

Respectfully submitted,

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